

## REMARKS

Claims 1-41, 43, and 44 are pending in the present application. Claims 31-41, 43 and 44 are withdrawn as being directed to non-elected inventions. Claims 1, 9, 20 and 24 are amended herein for clarity and to more particularly define the invention. Support for these amendments is found throughout the specification, as set forth below. No new matter is added by these amendments and their entry is respectfully requested. In light of the amendments presented herein and the following remarks, applicants respectfully request reconsideration of the pending application and the allowance of the pending claims to issue.

### **I. Claim Objections.**

The Action states that claims 9 and 24 are objected to. Specifically, the Action states that the notation of "MWCO" recited in claims 9 and 24 is allegedly unclear. Action, page 3.

Claims 9 and 24 are amended herein to recite molecular weight cut-off (MWCO). Support for this amendment can be found on page 20, line 2, of the specification. No new matter is added by this amendment. Accordingly, Applicants respectfully submit that the objection is overcome and respectfully request its withdrawal.

### **II. Claim Rejections under 35 U.S.C. § 112, second paragraph.**

The Action states that claims 1-21 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Action, page 3.

**A.** Specifically, the Action states that it is not clear whether the meal or flour that is being separated from the solvent is the same oil-free meal or flour that was first contacted with the organic solvent. Action, page 3-4. The Action further states that it is not clear how the organic solvent is intended to limit the method and what relationship is intended between the first step of contacting the oil-free meal with the organic solvent and the second step of separating the meal from the solvent. Action, page 4.

Claim 1 is amended herein to recite a process for preparing an angiotensin converting enzyme (ACE) inhibitory peptide-containing hydrolysate comprising: a) contacting a substantially oil-free seed meal or a flour with an organic solvent, b) separating the meal or flour of step (a) from the solvent, and c) treating the separated meal or flour of step (b) with at least one proteolytic enzyme to produce an ACE inhibitory peptide-containing hydrolysate. No new matter is added by this amendment. Accordingly, applicants respectfully submit that claim 1 is now clarified and respectfully request that the rejection under 35 U.S.C. be withdrawn.

**B.** The Action states that it is not clear how the recitation of w/w in claims 12, 13 and 26 is intended to limit the claims in the absence of a "standard or "reference" to which the proteolytic enzyme concentration is relative to. Action, page 4.

Applicants respectfully submit that "w/w" is used routinely in the art and as such one of ordinary skill in the art would recognize the meaning of the recitation "w/w" as it is used in claims 12, 13 and 26. Further, the specification on page 6, lines 30-31, provides a more detailed explanation of "w/w", wherein it states [t]ypically, the proteolytic enzyme is used at a concentration from about 0.25% to about 8.0% w/w (enzyme:protein content). Thus, based on what was known in the art at the time of the filing of the present application, in addition to the description of w/w provided in the application itself, one of ordinary skill in the art would clearly understand the meaning of w/w as it is used in claims 12, 13 and 26.

Accordingly, Applicants respectfully submit that the objection to claims 12, 13, and 26 under 35 U.S.C. § 112, second paragraph, is overcome and therefore respectfully request that the rejection be withdrawn.

### **III. Claim rejections under 35 U.S.C. § 102(b).**

The Action states that claims 1, 3-7, 10-11 and 14-16 stand rejected for allegedly being anticipated by Wu et al. (*J. Agric. Food Chem.* 49: 501-506 (2001)) as evidenced by Garrison et al. (U.S. Patent Application No. 4,175,075). Action,

page 4. Specifically, the Action states that Wu et al. discloses contacting a defatted soy meal with Alkalase to yield ACE inhibitory peptides. Action, page 4.

Applicants respectfully submit that Wu et al. does not discuss a process for preparing an angiotensin converting enzyme (ACE) inhibitory peptide-containing hydrolysate comprising: a) contacting a substantially oil-free (i.e., defatted) seed meal or a flour with an organic solvent (thus, effecting a further extraction), b) separating the meal or flour of step (a) from the solvent, and c) treating the separated meal or flour of step (b) with at least one proteolytic enzyme to produce an ACE inhibitory peptide-containing hydrolysate as recited in claim 1. As such, Wu et al. does not disclose all of the recitations of claim 1 or of its dependent claims as required for a rejection under 35 U.S.C. § 102.

Wu et al. does not discuss how the soy meal was defatted or any method of extraction of the soy meal with an organic solvent. Additionally, Wu et al. does not discuss a subsequent extraction step of the defatted seed meal prior to treatment with the Alkalase, as recited in step (a) of claim 1 of the present invention. However, the Action states that Garrison et al. "teach defatting of oleaginous seeds rich in lipids with extraction using water-alcohol systems at temperature ranges from room temperature to the boiling point of the solvent to provide high quality protein." Action, page 5. Based on this, the Action concludes that Wu et al. would inherently result in the claimed method. *Id.* Applicants respectfully disagree with this interpretation of Garrison et al. and the conclusion in the Action that Wu et al. inherently results in the method of the present invention.

As an initial point, it is noted that the legal standard for inherency, as set forth in section 2112 in the MPEP, states that "[t]o establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." (In re Robertson, 169 F.3d 743, 745, 49

USPQ2d 1949, 1950-51 (Fed. Cir. 1999)). (Emphasis added.) The MPEP also cites Ex parte Levy as stating that "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." (17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (Emphasis in original)). It is clear from these cases that in order for the standard for inherency to be properly cited in an anticipation rejection, 1) the allegedly inherent characteristic must necessarily flow from the teachings of the cited art; 2) such an inherent disclosure must be recognized as such by a person of ordinary skill in the art; and 3) such a determination must be supported by fact or technical reasoning.

In the present case, the allegedly inherent characteristic does not necessarily flow from the teachings of the prior art. Garrison et al. describes the prior art process of defatting of vegetable seeds as being done either by extraction "with a solvent, e.g., hexane, or pressed to remove the oil and lipid materials" (Garrison et al., col. 1, lines 35 to 39 and col. 6, lines 24 to 29). Garrison et al. does not describe the water/alcohol extraction as being part of the defatting process as alleged in the Action. In fact, the focus of Garrison et al. is not on the defatting process but rather on a density fractionation process for recovering vegetable seed protein granules (Garrison et al., Abstract and col. 1, lines 64-68).

The process described in Garrison et al. involves the preparation of protein granules from comminuted, lipid-containing vegetable seed matter by first treating that matter with an aqueous solution of an electrolyte and carbohydrate, followed by separation of the protein granules by centrifugation (Garrison et al., column 7, lines 50 to 55 and col. 8, lines 15 to 17). A further process is then described in which the isolated protein granules are defatted by conventional means using solvent extraction with hexane (Garrison et al., col. 8, lines 36 to 39). The last step is an extraction with a water/alcohol mixture and is described as further concentrating the protein by dissolving and carrying away any residual non-proteinaceous components, principally extraneous carbohydrates (Garrison et al., col. 8, lines 40 to

55). Clearly, since oil seeds contain little or no carbohydrate, this step is carried out to remove the residual carbohydrate which was added to the seed material in the initial density fractionation process. Unless carbohydrates are added to the mixture as is done in the density fractionation process of Garrison et al., there would be no reason to carry out this step. It is a step that is specific to the density fractionation process described therein and is unrelated to the defatting process. Therefore, contrary to the assertion in the Action, the subsequent extraction step of Garrison et al. would not inherently be part of a conventional defatting process for soy meal such as might be used in Wu et al. and thus, would not be recognized as an inherent part of the Wu et al. process by a person of ordinary skill in the art.

Clearly, the requirements needed to demonstrate that the methods of the claimed invention are inherently disclosed in the Wu et al. reference have not been met. The allegedly inherent characteristic as evidenced by Garrison et al. does not necessarily flow from the teachings of Wu et al., the inherency alleged to be present in Wu et al. would not be recognized as such by one of ordinary skill in the art and there is no support in fact or technical reasoning for the determination that Wu et al. inherently discloses the claimed invention. Therefore, the claimed methods of this invention cannot be anticipated as inherent in the teachings of Wu et al. as evidenced by Garrison et al. For at least these reasons, applicants believe this rejection has been overcome and respectfully request its withdrawal.

#### **IV. Claim rejections under 35 U.S.C. § 103(a).**

**A.** The Action states that claims 1, 2, 8, 9, 12, 13, 17, 18 and 19-21 stand rejected as allegedly being unpatentable over Wu et al. and Garrison et al. in view of Eto et al. (*J. Jpn. Soc. Nutr. Food Sci.* 51:355-359 (1998)). Action, page 6. Specifically, the Action states that in view of Wu et al. it would have been obvious to one of ordinary skill in the art at the time the invention was made to make adjustments to conventional working conditions as merely a matter of judicious selection and routine optimization for providing a means for the expected result of proteolytic cleavage of proteins in soy meal. Action, page 7-8. Applicants respectfully traverse this rejection.

As discussed above, Wu et al. fails to disclose each element of the present invention. Further, Garrison et al. and Eto et al fail to remedy the deficiencies of Wu et al. As described above, the step in Garrison et al. of extracting with a water/alcohol mixture is not part of the defatting process as the Action is contending, but rather is a further step to remove carbohydrates added in the first step of the Garrison et al. density fractionation process. Unless carbohydrates are added to the mixture as is done in Garrison et al., one of ordinary skill in the art would have no motivation to perform the water/alcohol extraction step of Garrison et al.

Furthermore, Garrison et al. focuses on producing whole vegetable protein for nutritional uses and does not teach or suggest proteolysis of vegetable seed proteins to produce ACE-inhibitory peptides or any other type of proteolytic products. There is therefore nothing in the teachings of Garrison et al. to suggest that the water/alcohol extraction process that is applied to purified protein granules to remove the carbohydrate added in the earlier density fractionation step in Garrison et al. could be applied to whole, substantially oil-free seed meal to improve the ACE-inhibitory activity of a hydrolysate prepared from that meal as described by the present invention.

Moreover, applicants respectfully submit that, in fact, when read as a whole Garrison et al. teaches away from the present invention. It is noted, in column 1, lines 32 to 43, that Garrison et al. describes how the protein of oleaginous or oil bearing seeds "is usually obtained in the form of isolate or concentrate by extraction of the defatted seeds". The principal interest with oil-bearing seeds is generally to obtain oil for human consumption. Accordingly, "the vegetable seeds are first comminuted or ground to form flakes, meals or flours which are either extracted with a solvent, e.g., hexane, or pressed to remove the oil and lipid materials. The defatted mass can be washed with a water-alcohol solution to dissolve and remove soluble, residual cellular materials and yield a concentrate. Concentrates, however, generally have low protein contents" (Garrison et al., col. 1, lines 41 to 43; emphasis added). Clearly, one of ordinary skill in the art seeking to maximize

protein recovery and enzyme inhibitory activity would not choose the procedure of Garrison et al. Accordingly, applicants respectfully submit that Garrison et al. teaches away from the claimed process, suggesting as it does that defatting seed meal and washing the defatted material with a water-alcohol solution leads to a concentrate with low protein recovery.

Finally, the Action states that with respect to claim 20, Eto et al. teaches that it is known in the art to obtain a hydrolysate that contains the ACE-inhibitory peptide Phe-Leu. Action, page 8. Claim 20 is amended herein to recite the process of claim 1, wherein the seed meal is canola meal and the hydrolysate contains the peptide Val-Ser-Val. Therefore, claim 20 having been amended, applicants respectfully submit that this rejection has been overcome.

Accordingly, applicants respectfully submit that Wu et al., Garrison et al. and Eto et al., whether viewed singly or in combination, fail to teach or suggest the claimed method of the present invention.

In view of the foregoing, applicants respectfully submit that the rejection of claims 1, 2, 8, 9, 12, 13, 17, 18 and 19-21 under 35 U.S.C. § 103(a) in view of Wu et al., Garrison et al. and Eto et al. is overcome and respectfully request that it be withdrawn.

**B.** The Action states that claims 22-30 stand rejected as allegedly unpatentable over Wu et al. further in view of Tzen et al. (*Plant Physiol.* 101:267-276 (1993)). Specifically, the Action states that Wu et al. differs from the base claim 22 by not explicitly disclosing treatment of an oil-free flax seed meal or canola meal with Alcalase 2.4L for preparing ACE-inhibitory peptides. Action, page 9. The Action further states that Tzen et al. discloses that it is known in the art that oil-containing seeds such as flax and soybean also contain proteins (oleasins) among their contents. *Id.* On this basis, the Action concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the proteinaceous flax seeds with the ACE-inhibitory peptide isolation processes

described by Wu et al. for the known and expected result of providing a means recognized in the art to recover ACE-inhibitory peptides from seeds rich in proteins. Action, page 10. Applicants respectfully traverse this rejection.

As an initial point, flax and canola are completely unrelated species, botanically, to soybeans. Additionally, it was known to those of ordinary skill in the art at the filing date of this application that many plant materials contain an abundance of protein but do not yield good ACE-inhibitory peptides on proteolytic hydrolysis. It was also well-known in the art at the time of the filing of the present application that plant proteins differ widely in their amino acid composition. It is for this reason that the proteins of flax and canola are considered to be nutritionally inferior to the proteins of soy and, as a result, trade at a discount compared to soy. Further, Tzen et al. does not offer any comparison between the oleosin proteins of flax and canola and the proteins of soy meal such that one could conclude that the oleosins of flax and canola would yield ACE-inhibitory peptides on proteolytic hydrolysis similar to that of soybean. Therefore, one of ordinary skill in the art would not find it obvious that because soy meal yields good ACE-inhibitory activity, the same would be true for flax and canola.

Furthermore, Tzen et al. discloses studies which characterise the structure and components of oil seed oil bodies. Oil bodies are the oil storage units in which plants such as rape, flax, maize, etc., store their oil content. As noted in Tzen et al., these oil bodies comprise spherical particles the shell of which comprises a mono layer of phospholipids embedded with proteins called oleosins. These proteins form a very small part of the total protein content of an oil seed; Tzen et al. estimates the oleosins to be 7.2% of total seed protein (Tzen et al., page 275). Tzen et al. does not discuss any proteins other than these oil body proteins. Therefore, the teachings of Tzen et al. would not be relevant to someone seeking to recover ACE-inhibitory peptides from the protein rich fraction of an oil seed.



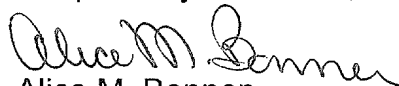
Accordingly, nothing in Tzen et al. teaches or suggests that the oleosin proteins of flax and canola, or any other proteins of these species, would yield ACE-inhibitory peptides.

Therefore, applicants respectfully submit that Wu et al. and Tzen et al., alone or in any combination, do not render obvious the presently claimed invention. Thus, applicants respectfully request that the rejection of claims 22-30 under 35 U.S.C. § 103(a) in view of Wu et al. and Tzen et al. be withdrawn.

Having addressed all of the issues raised by the Examiner in the present Office Action, Applicants believe that the present application is in condition for allowance, which action is respectfully requested. The Examiner is encouraged and invited to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue.

The Commissioner is authorized to charge Deposit Account No. 50-0220 in the amount of \$1020.00 as a fee for a three-month extension of time. This amount is believed to be correct. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



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